

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:1398
ANSWERED ON:29.10.2008
BIOSIMILAR PRODUCTS
Muqueem Shri Mohammed

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the Biosimilar products from the overseas countries have been allowed to be sold in the country;
- (b) if so, the details thereof;
- (c) whether Biosimilars are being manufactured in the country; and
- (d) if so, the details thereof including the names of the companies and their products?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) & (b) : Yes Sir The biosimilar product which have been found to be safe and efficacious on examination as per norms stipulated in schedule-Y to the Drugs and Cosmetics Rules, 1945 are permitted to be marketed in the country.

(c)& (d) : Yes Sir. The major manufacturers of these products in the country are as under:

M/s Biocon Limited, Bangalore-Res-Hum. EPO Inj. And nimotuzmad inj.
M/s Bharat Biotech, Hyderabad-Streptokinase inj.
M/s Cadila Health Care, Ahmedabad-IFN alpha 2b inj.
M/s Wockhard Ltd, Pune- Recombinant Hu IFN Alpha 2b Inj rec. Hum EPO Inj.
M/s Shantha Biotec Hyderabad-IFN Alpha 2b Inj.
M/s Dr. Reddy's Lab, Hyderabad-Rituximab, GCSF, inj.
M/s Intas pharma, Ahmedabad- Recombinant Human Reg GCSF Inj.
M/s Shreya Life Science Pvt. Ltd. Pune-R-hu Inulin Inj.
M/s Zenoteech Lab Hyderabad, Rintuximab, r-hu GCSF inj,R-hu GMCSF
M/s Bharat Serum and Vaccines Ltd., Pune-FSH Inj.
M/s Genova Bio Pharmaceuticals Ltd., Pune - R-hu GMCSF Inj.